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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,566	11/14/2003	Yong-Qian Wu	3004-A	8262
29035	7590	01/12/2005	EXAMINER	
GUILFORD PHARMACEUTICALS, INC. 6611 TRIBUTARY STREET BALTIMORE, MD 21224			DESAI, RITA J	
			ART UNIT	PAPER NUMBER
			1625	
DATE MAILED: 01/12/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/713,566

Applicant(s)

WU ET AL.

Examiner

Rita J. Desai

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1.0 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-62 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-19 in part , drawn to compounds and pharmaceutical compositions, classified in various classes and subclasses . A further election of a single disclosed species is required. This group may be subject to further restriction.
- II. Claims 20 I part , drawn to a complex composition with additional agents, classified in class 514, 424 and various subclasses.
- III. Claims 10-26 in part , drawn to a method of contacting with a cyclophilin type immunophilin, classified in various classes and subclasses. A further election of a single disclosed species is required. May be subject to further restriction.
- IV. Claims 27 , 28 in part , drawn to a complex of compound of formula 1 and a cyclophilin type immunophilin , classified in various classes and subclasses. A further election of a single disclosed species is required. This group is subject to further restriction.
- V. Claims 29-38 in part , drawn to method of treating a neurological disease , classified in various classes and subclasses. A further election of a single disclosed species is required. May be subject to restriction.
- VI. Claims 39 in part , drawn to a method of preventing a neurological disorder, classified in various classes and various subclasses. A further election of a single disclosed species is required. Subject to further restriction.

- VII. Claim 40-46 in part , drawn to method of stimulating hair growth , classified in various classes and subclasses. A further election of a single disclosed species is required. Subject to further restriction.
- VIII. Claims 47 in part , drawn to a method of inhibiting breakdown of mitochondrial metabolism in cells , classified in various classes and subclasses. A further election of a single disclosed species is required.
- IX. Claims 48, 51 in part , drawn to a method of preventing or delaying death cell and classified in various classes and subclasses. A further election of a single disclosed species is required. May be subject to further restriction.
- X. Claims 49 in part, drawn to method of preventing , mitigating or delaying excitotoxic , classified in various classes and subclasses. A further election of a single disclosed species is required. May be subject to further restriction.
- XI. Claim 50 in part , drawn to a method of inhibiting breakdown of energy metabolism and cell death classified in various classes and subclasses. May be subject to further restriction. A further election of a single disclosed species is required.
- XII. Claims 52-54 in part , drawn to a method of treating ischemic heart disease , classified in various classes and subclasses. May be subject to further restriction. A further election of a single disclosed species is required.
- XIII. Claims 55, 56 in part , drawn to a method of treat an ophthalmic disorder , classified in various classes and subclasses. This group may be subject to further restriction. A further election of a single disclosed species is required.

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- XIV. Claims 57 in part , drawn to method of treating Reye's syndrome , classified in various classes and various subclasses. A further election of a single disclosed species is required. Subject to further restriction.
- XV. Claim 58 in part , drawn to method of preventing or reducing tissue damage, classified in various classes and various subclasses. A further election of a single disclosed species is required. May be subject to further restriction.
- XVI. Claims 59-61 in part , drawn to a method of treating an infection or infestation with a protozoan or helminthic parasites, classified in various classes and subclasses. A further election of a single disclosed species is required. May be subject to further restriction.
- XVII. Claim 62,63 in part , drawn to a method of treating viral disease, classified in various classes and subclasses. A further election of a single disclosed species is required . May be subject to further restriction.

The inventions are distinct, each from the other because of the following reasons:

Inventions I to III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are different the compounds of claims 1-19 have only a benzene ring as its common core. The variables X and V and Y have so many variables and permutations and combinations that a 102 on one group would not be a 103 on the other. These compounds have different modes of operations and different bonding.

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Inventions I- III and IV to XVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compounds are unrelated and the various methods of treating using these compounds are also unrelated , since there are other available drugs that can be used to treat the various neurological and ischemic, viral, infectious and such diseases as given.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

A telephone call was made to Mr. Hansjorg Sauer on 1/6, 1/7 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

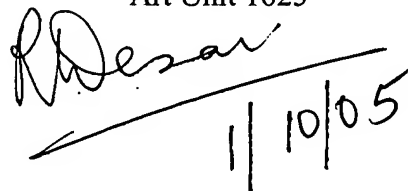
Applicants preserve their right to file a divisional on the cancelled non-elected claims without prejudice

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rita J. Desai
Primary Examiner
Art Unit 1625


11/10/05

R.D.
January 10, 2005